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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,464	05/24/2001	Saverio C. Falco	BB1193 USDIV	3016

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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/864,464	FALCO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kathleen M Kerr	1652	

-- Th **MAILING DATE** of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 31-66 is/are pending in the application.
- 4a) Of the above claim(s) 44-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a written restriction requirement (mailed on March 27, 2003), Applicants filed an election and amendment received on May 12, 2003. Said amendment amended Claims 31-36. Thus, Claims 31-66 are pending in the instant Office action.

### ***Election***

2. Applicant's election without traverse of Group I, Claims 31-43, in the response received May 12, 2003 (faxed to the Examiner October 16, 2003) is acknowledged. Claims 31-66 are pending in the instant application. Claims 44-66 are withdrawn from further consideration as non-elected inventions. Claims 31-43 will be examined herein.

### ***Priority***

3. The instant application is granted the benefit of priority for the U.S. non-Provisional Application No. 09/864,464 filed July 20, 1999 (divisional parent) as requested in the first lines of the specification. While the application is also granted the benefit of U.S. Provisional Application No. 60/093,530 filed July 21, 1998 as requested in the first lines of the specification, the subject matter (SEQ ID NOs:9/10) are not disclosed therein. Thus, the pending claims are granted priority only to July 20, 1999.

***Information Disclosure Statement***

4. No information disclosure statement has been filed with the instant application as of the date mailed of the instant Office action. Applicants are reminded that they have a duty to disclose all information, of which they are aware, relevant to the patentability of the pending claims (see 37 C.F.R. § 1.56 and M.P.E.P. § 2000).

***Oath/Declaration***

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by application number and filing date is required. See M.P.E.P. § 602.01 and 602.02.

The oath or declaration is defective because: the signatures of the inventors are not dated, i.e., the date of the execution of the declaration unknown. Said date is required by M.P.E.P. § 602.

***Sequence Compliance***

6. By virtue of the sequence listing filed on August 2, 2002, the instant application fully complies with the sequence rules.

***Objections to the Specification***

7. The specification is objected to because the title is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are drawn (see M.P.E.P. § 606.01). The Examiner suggests the following new title:

---Polynucleotides Encoding Lysyl-tRNA Synthetase from *Zea mays*---

8. In the specification, the Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of the full name of all the source species, *Zea mays*, *Oryza sativa*, *Glycine max*, and *Tritium aestivum*, for completeness.

### ***Claim Objections***

9. Claim 31 is objected to for using an improper article. In line 2, the phrase “an lysyl-tRNA synthetase” should be ---a lysyl-tRNA synthetase---. Correction is required.

10. Claims 31-34 are objected to for improperly limiting % identity between sequences. Two sequences cannot “have 80% identity” – they can ---share 80% identity---. Correction is required.

### ***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 37-40 and 42-43 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In each claim, the phrase “the polynucleotide of claim 31” or “the chimeric gene of claim 37” (emphasis added) is used; however, Claim 31 is drawn to a genus of polynucleotides (more than one) so the article ---a--- is appropriate to indicate any of the polynucleotides of Claim 31. Correction is required.

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12. Claim 41 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The antecedent basis of "the chimeric gene of claim 31" is unclear since Claim 31 is drawn to a polynucleotide. Claim 41 should be drawn to Claim 37, drawn to a chimeric gene. Correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 31-34 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for any polynucleotide that encodes SEQ ID NO:10, does not reasonably provide enablement for polynucleotides with such low sequence identity, such as the 80% identity claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The amount of experimentation required of one of skill in the art to make the claimed invention to the full extent of its scope is undue.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404).

Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

The instant specification teaches SEQ ID NO:10, a lysyl-tRNA synthetase from *Z. mays*, and SEQ ID NO:9, a *Z. mays* gene exactly encoding SEQ ID NO:10. The functionality of this sequence appears to be assigned by way of homology studies and not by direct experimentation; SEQ ID NO:10 is only 68% identical to the lysyl-tRNA synthetase from *A. thaliana* (see page 19 of the specification). The art includes several examples of lysyl-tRNA encoding genes (see, for example, Giritch *et al.*); however, few of these are from plants. The art fully enables any DNA encoding SEQ ID NO:10 based on the degeneracy of the genetic code. While the instant specification describes and enables means for identifying other lysyl-tRNA synthetase genes using hybridization methods, etc., these methods do not enable one of skill in the art to make all, or a relevant portion of, the polynucleotides within the scope of the claims because the ability to find a lysyl-tRNA synthetase gene, which is structurally related to SEQ ID NO:9, is not equivalent to the ability to make a lysyl-tRNA synthetase gene as required by the statute (i.e.,

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“make and use”). No description in the specification or the art provides particular residues whose encoding is important within the disclosed sequence so that its lysyl-tRNA synthetase - nature is maintained. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to make such members. Therefore, the instant claims are not enabled to the full extent of their scope.

#### ***Closest Prior Art***

14. The closest prior art to the claimed invention is found in genes encoding lysyl-tRNA synthetases from other plants. The gene from *A. thaliana* (GenBank Accession Number AF125574) encodes a protein that is 69% identical to SEQ ID NO:10; the gene from *L. esculentum* (GenBank Accession Number X94451) encodes a protein that is 63% identical. Thus, the claimed invention is free of the prior art. The Examiner notes, however, that the starting amino acid is a leucine, not a methionine -- thus, whether or not the gene in SEQ ID NO:9 is a full-length gene is unclear. The two known plant sequences are 602 and 588 amino acids long. Thus, SEQ ID NO:10, having 634 amino acid residues, appears to be well within the range of a full-length protein, such that lysyl-tRNA synthetase activity could be expected.

#### ***Conclusion***

15. Claims 31-43 not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

November 20, 2003

